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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/783,981	02/16/2001	Francoise Leclercq	03806.0500	2816

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EXAMINER

EPPS, JANET L

ART UNIT	PAPER NUMBER
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1635

DATE MAILED: 06/03/2003

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Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/783,981

Applicant(s)

LECLERCQ ET AL.

Examiner

Janet L. Epps-Ford

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 24 March 2003.
- 2a) ☒ This action is FINAL. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 23-42 is/are pending in the application.
- 4a) Of the above claim(s) 39-42 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 23-38 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____

DETAILED ACTION

1. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Response to Arguments

2. Claims 23-33 remain rejected under 35 U.S.C. 103(a) as being unpatentable over Zanta et al. in view of Neidigh et al. for the reasons of record set forth in the Official Action mailed 1-14-2003.

Applicant's arguments filed 3-24-03 were fully considered but are not persuasive. Applicants traverse the instant rejection on the grounds that "there is no teaching or suggestion in the references that the method of Neidigh et al. is useful for coupling hemiacetals, especially functionalized hemiacetals with other reactive groups, to polyalkyleneimines." Additionally, Applicants argue that the Examiner has not "provided any evidence that one skilled in the art would have a reasonable expectation of success in (1) leaving out triethylamine or (2) using Neidigh's disclosed reaction conditions to couple a functionalized hemiacetal to a polyalkyleneimine."

Contrary to Applicant's assertions, one of ordinary skill in the art would have had a reasonable expectation of success in using the Neidigh et al. reaction conditions to couple a functionalized hemiacetal to a polyalkyleneimine since this reaction comprises a reductive amination reaction, and the process of Neidigh et al. clearly provides a means for reductive amination of aldehyde or ketone compounds, see Scheme I. Moreover, Neidigh et al. teach that "[T]he scope of the method proved to be quite general for a variety of aldehydes, and ketones," see page 2527, last paragraph. Additionally, in regards to leaving out the triethylamine, it is

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noted that the instant claims are drawn to a process comprising treating a polyalkyleneimine with a functionalized hemiacetal in the presence of titanium (IV) isopropoxide and sodium borohydride. The breadth of the instantly claimed process encompasses the use of triethylamine. Therefore, it is not necessary that the process of Neidigh et al. leave out triethylamine in order to render obvious the claimed process.

Moreover, the Zanta et al. reference provides a method for functionalization of polyethyleneimine by means of glycosylation (see Figure 1, page 841), wherein the glycosylation method comprises reductive amination, wherein the method comprises the use of sodium borate (see page 840, 7th paragraph). Additionally, one of ordinary skill in the art would recognize that the glucose subunit of lactose used in Scheme I is a cyclic hemiacetal. Absent evidence to the contrary, "[W]here the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation." (See MPEP § 2144.05). In the instant case, Zanta et al. provides the general conditions necessary for reductive amination of a polyethyleneimine with a hemiacetal-containing compound.

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Claim Rejections - 35 USC § 112

3. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

4. Claims 34-38 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 34 recites the phrase "the reaction," there is insufficient antecedent basis for this limitation in the claim. Additionally, claim 34 recites "targeting element," however the metes and bounds of this phrase is vague and indefinite since the claim does not indicate what the compound is targeting, and it does not define the structure of this element. One of ordinary skill in the art would not be reasonably apprised of the scope of the claimed invention, since neither the specification as filed nor the claims provides an adequate definition of the term "targeting element" as used in this context.

Conclusion

5. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

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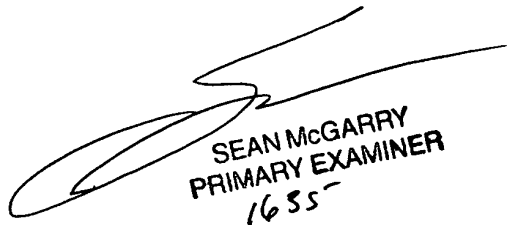
6. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Janet L. Epps-Ford whose telephone number is 703-308-8883. The examiner can normally be reached on M-T, Thurs-Fri, 8:30AM-7:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, John L. LeGuyader can be reached on 703-308-0447. The fax phone numbers for the organization where this application or proceeding is assigned are 703-305-3014 for regular communications and 703-746-5143 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.

Janet L. Epps-Ford
Examiner
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JLE
June 2, 2003


SEAN MCGARRY
PRIMARY EXAMINER
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